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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,870	06/23/2000	John D Brennan	086671/0109	1416

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/13/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/599,870

Applicant(s)

BRENNAN ET AL.

Examiner

Pensee T. Do

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 50-65.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

A previous advisory action was sent on March 7, 2003 stating that the after-final response was not entered because of a new matter issue in the specification, i.e. changing from "bimolecular" to –biomolecular—. However, after close reconsideration, the word –biomolecular—was previously in the present specification. Thus, the previous advisory action was disregarded. The interview summary on April 21, 2003 stating that prosecution for this application was to be re-opened. However, it is unnecessary for re-opening prosecution on this application because the mistake was on the advisory action, which happened after prosecution was closed.

Amendment Entry & Claim Status

The after-final response sent on January 22, 2003 was entered.

In the amendment to the claim, it is noted that applicant amended claim 55 which was previously a dependent claim from claim 54. However, claim 55 is now an independent claim. It is suspected that applicant meant to amend claim 50 instead of claim 55. Please verify.

Claims 50-65 are now pending.

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-65 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The reversibly disrupting factor, i.e. thermal, urea, GdHCl, is a critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention- the instant invention is directed to a carrier comprising a matrix of organic, inorganic, or organic and inorganic material and containing a biomolecular interaction entrapped within the matrix, wherein the biomolecular interaction comprises two or more biological species that can be reversibly dissociated from the other.

The state of the prior art- the prior art fails to teach a carrier comprising a matrix of inorganic, or organic, or organic and inorganic material and a biomolecular interaction entrapped within the matrix wherein the biomolecular interaction comprises two or more species that can be reversibly dissociated from the other.

The predictability or lack thereof in the art- in view of the lack of teachings in the prior art that shows or suggests a biomolecular interaction, entrapped within the matrix, wherein the biomolecular interaction comprises two or more species that can be reversibly dissociated from the other, the level of predictability is low. While it may be possible to reversibly dissociate the biological species of the biomolecular interaction by adding GdHCl or urea or subjecting the biomolecular interaction under thermal condition as described in the instant specification, it has not been shown that the biomolecular interaction can be reversibly dissociated by itself or by adding other compounds.

The amount of direction or guidance present – the instant specification provides guidance for reversibly dissociating the biomolecular interaction using only urea, GdHCl, or subjecting such biomolecular interaction to thermal condition- see example 3, page 32.

The absence of working examples – the examples disclosed in the specification only show reversibly dissociating the biomolecular interaction by adding urea, GdHCl or thermal condition.

The quantity of experimentation necessary – it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed.

The relative skill of those in the art- the level of skill in the art is high.

The breadth of the claims – the claimed carrier comprises a matrix of organic, inorganic, or organic and inorganic material and a biomolecular entrapped within the

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matrix wherein the biomolecular interaction comprises two or more biological species that can be reversibly dissociated from each other.

The instant specification describes that the biological species of the biomolecular interaction can be reversibly dissociated from each other only when a reversibly disrupting factor such as urea, GdHCl, or thermal is applied. Without such reversibly disrupting factor, the complex or biomolecular interaction would not be disrupted and thus reversibly dissociation would not take place. The instant specification fails to teach any other possible factor which would reversibly dissociate the biomolecular interaction or that the biomolecular interaction would reversibly dissociate on its own-without the aid of a disrupting factor. At best, the instant specification is enabled for a carrier comprising a matrix of organic, inorganic, organic and inorganic material, a biomolecular interaction entrapped within the matrix, wherein the biomolecular interaction can be reversibly dissociated from each other when adding urea, GdHCl, or thermal/heat, but the specification is not enabled for a biomolecular interaction that can reversibly dissociate on its own or by any other compounds. An undue amount of experimentation would be required to identify any possible reversibly dissociating compounds for reversibly dissociating the biomolecular interaction entrapped within the matrix of the carrier.

Response to Arguments

Applicant's arguments filed on January 22, 2003 have been fully considered but they are not persuasive.

Applicant argues that the claims do not need to be limited to specific dissociating factors since the invention is not directed to novel biomolecular interactions. The claims are currently directed to a carrier that comprises a biomolecular interaction entrapped within a matrix, wherein the biomolecular interaction comprises at least two biological species that can be reversibly dissociated from the other within the matrix. The ability to reversibly dissociate within the matrix is important and is a characteristic that defines the carrier claimed. Applicant also argues that a person skilled in the art would appreciate that denaturations or other molecules, such as antagonists of the biomolecular interaction, can cause the reversible dissociation in the invention.

Applicant submits that the invention is directed to a carrier that comprises a biomolecular interaction entrapped within a matrix, wherein the biomolecular interaction comprises at least two biological species that can be reversibly dissociated from the other within the matrix. For two species of a biomolecular interaction to be reversibly dissociated from each other, an external factor must be present for catalyzing such reverse dissociation. Such external factor can be heat, or pH as applicants has mentioned. However, for the dissociation to happen within the matrix, such factor must be present within the matrix of the carrier. These biological species cannot dissociate by themselves within the matrix of the carrier. One of ordinary skills in the art would find that the biological species could reversibly dissociate using a denaturation molecule or an antagonist in other environment other than within the matrix of a carrier. One of ordinary skills in the art would not be able to know that the biological species reversibly dissociate within the matrix of a carrier using the same conventional denaturation

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molecules or antagonists. Thus, the conditions or factors that promote the dissociation of the biological species within the matrix of a carrier must be specified.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
March 5, 2004


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